

## WORK INSTRUCTIONS MASSACHUSETTS COMPLIANCE

This document gives an outline of the processes to be used by the Product Testing Laboratory for the processing and testing of samples to comply with Massachusetts regulations dated August 19, 1997.

### Receipt of Samples from Territory Sales Managers

1. Representative from PTL will personally obtain shipment at loading dock.
2. The mail person and the PTL representative will sign the shipping document.
3. The signed document will be retained by PTL.
4. The PTL representative will escort samples to PTL Customer Relations.

### PTL Sample Receiving

1. Open each mailing package and sort brands.
2. Ensure packs obtained match enclosed affidavit, (total number of packs and only two packs per store). Brands with incomplete number of packs or errors in sampling need to be addressed with Sales.
3. Composite each brand and place in white cartons. Place incomplete samples aside.
4. From those brands with all required packs, receive four (4) brands per one request as:
  - a. Begin each request with the prefix MA.
  - b. Follow with the 2 digit year.
  - c. Follow with a dash and sequence number, (example: MA97-1, MA97-2,...).
5. The tests, replicates, and number of cigarettes per replicate are listed below:

| Test       | Number of<br>Repl. Per Test | Number of Cigarettes<br>per Replicate |
|------------|-----------------------------|---------------------------------------|
| TIP-LENGTH | 20*                         | 1                                     |
| FTC-BUTT   | 1**                         | 1                                     |
| MA-TPM     | 20                          | 5                                     |
| MA-PUFF    | 20                          | 5                                     |
| MA-NIC     | 20                          | 5                                     |
| MA-H2O     | 20                          | 5                                     |
| MA-TAR     | 20                          | 5                                     |
| MA-CO      | 20                          | 5                                     |
| EVENT      | 100                         | 1                                     |
| E-CTBWT    | 3                           | 50                                    |
| E-CWT      | 3                           | 50                                    |
| E-P+PWT    | 3                           | 50                                    |
| MA-PH      | 5                           | 1                                     |
| MA-NIC-FLR | 3                           | 50                                    |

\* Manually documented after all packs are opened.

\*\* Calculated as TIP-LENGTH + 3

6. Deliver samples, request form, and barcode cards to the sample prep lab.

**Sample Preparation**

1. Carefully open each cigarette pack since all packs need to be retained. Make sure pack label stays with each cigarette pack.
2. Prepare four (4) equilibration trays by affixing a barcode label to each tray. Write the appropriate test designation on each label: Smoke, Vent, Nic-Flr, or pH.
3. Sort cigarettes into equilibration trays as follows:

| Tray Designation | Number of Cigt. From Each Pack | Equilibration Conditions | Total Number of Cigt. In Tray |
|------------------|--------------------------------|--------------------------|-------------------------------|
| Smoke            | 2                              | ISO                      | 100                           |
| Vent             | 2                              | ISO                      | 100                           |
| Nic-Flr          | 3                              | ISO                      | 150                           |
| pH               | 1                              | ISO                      | 50                            |

3. Leave all remaining cigarettes in the specific pack and return the pack to the appropriate carton.
4. Stored in L. Chamber's office.
5. Utilize the cigarettes in the "pH" equilibration tray to determine the tipping paper length of twenty cigarettes to 0.1 mm and record on back of barcode card.
6. Customer Relations manually enters the tipping paper lengths into the CQS database.
7. Using the average of the twenty tipping paper length results, round to the nearest 0.5 mm. Determine the FTC butt length as the average tipping paper length plus 3 millimeters. The butt length result is entered into the CQS by Customer Relations.
8. Mark the insertion and butt length on all cigarettes in the "Smoke" equilibration tray and on ten (10) cigarettes in the "pH" equilibration tray.
9. Apply Scotch Tape #600 horizontally to half the tipping paper on all 100 cigarettes in the "Smoke" equilibration tray and to the ten (10) marked cigarettes within the "pH" equilibration tray. No tape is applied to the cigarettes in the "Vent" and "Nic-Flr" equilibration trays.
10. Scan and place each sample in the ISO equilibration room.

**Tobacco Weight Determination**

1. Transfer cigarettes from the "Nic-Flr" equilibration tray to a labeled Tupperware container and deliver to the PT Lab.
2. Analyze fifty (50) cigarettes for each tobacco weight determination. (If additional cigarette(s) are needed, obtain from "pH" equilibration tray.)
3. Place all loose filler back into the Tupperware container, seal, and deliver to Customer Relations for delivery to ARD for MA-NIC-FLR analysis.

### **Ventilation Analysis**

1. Transfer cigarettes from the "Vent" equilibration tray to a labeled Tupperware container and deliver to the PT Lab.
2. Analyze all one hundred (100) cigarettes for ventilation. (If additional cigarette(s) are needed, obtain from the "pH" equilibration tray.)
3. Return all cigarettes to the container after testing and return the container to Customer Relations.

### **Nicotine-in-Smoke Sample Preparation**

1. Prepare the smoking group sheets for the four samples of a specific request over five smoking runs for a total of twenty smoking ports per sample.
2. When preparing the smoking run, place five cigarettes per port using the half-taped cigarettes from the "Smoke" equilibration tray.
3. Use ISO equilibrated IM#16 on each run. No tape is applied to the monitor.

### **Nicotine-in-Smoke Testing**

1. Perform all smoking on the Filtrona 435 smoking machine using the 45ml Puff Volume/30second Puff Cycle/2 second Puff Duration regimen under ISO conditions.
2. Smoke five half-taped cigarettes on each port and obtain TPM, puff count, and CO data. Take two (2) clearing puffs at the end of the smoking run.
3. Place TPM pads in large test tubes.
4. Use twenty (20) mL of extraction solution for each TPM pad.

### **pH Analysis**

1. Use half-taped cigarettes from the "pH" equilibration tray for this test.
2. Use degassed water for all determinations.
3. Smoke one cigarette per port using the developed apparatus.
4. Take two (2) clearing puffs after the last puff of each cigarette.
5. Transfer the fifty (50) mL of water from each impinger and the TPM pad to the 150 mL beaker.
6. Rinse the impinger orifice tube using the collected water sample in Step 5.
7. Place the pH electrode into the solution ten (10) minutes after the clearing puff and record the pH five (5) minutes later.
8. Analyze five (5) replicates per sample.

### **Data Reporting**

- Enter data for all tests, with the exception of the pH and MA-NIC-FLR tests, into the CQS system per routine procedure.
- pH data is manually entered into the CQS system by the Analytical Technician.
- Results obtained from ARD for the Nic-in-Filler test will be entered into the CQS system by Customer Relations.

**Data Analysis**

- The standard deviations utilized by the CQS system have been set very high to prevent application of the MAD outlier test on this data.
- The data for these samples must be transferred by an analyst to Excel utilizing Brio.
- Apply the Dixon Test to each data set.
- No more than two outliers may be thrown out by this outlier test.